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July 8, 1999 Date of Deposit

A. David Joran (Reg. No. 37/858)

eg. No. 37/858)

File No.: 1078/1B925US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Samuel J. Danishefsky et al.

Serial No.:

09/042,280

Group Art Unit: 1623

Filed:

January 13, 1997

Examiner: Lee, H.

For:

COLON CANCER KH-1 AND N3 ANTIGENS

July 8, 1999

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56 and §1.97, applicants wish to direct the Examiner's attention to the following disclosures of which applicants have become aware, or which were cited by the International Searching Authority in connection with the related PCT International Application:

Serial No.: 09/042,280 Fil d: January 13, 1997

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- 1. V. Bencomo *et al.*, "Synthesis of glycopeptides having clusters of *O*-glycosylic disaccharide chains. . .," *Carbohydrate Research*, <u>116</u>, c9-c12, 1983 (Ex. 2);
- 2. M. Elofsson et al., "Preparation of Tn and Sialyl Tn Building Blocks. . .," Tetrahedron, 53, 369-390, 1997 (Ex. 3);
- 3. M. Elofsson and J. Kihlberg, "Synthesis of Tn and Sialyl Tn building Blocks for Solid Phase Glycopeptide Synthesis," *Tetrahedron Letters*, 36, 7499-7502, 1995 (Ex. 4);
- 4. P. Fung et al., "Active Specific Immunotherapy of Murine Mammary...," Cancer Research, 50, 4308-4314, 1990 (Ex. 5);
- 5. R. Gleiter et al., "Synthesis and Properties of Eight-and Ten-Membered Selenaradialenes," *Tetrahedron Letters*, 35, 8779-8782, 1994 (Ex. 6);
- 6. P. Grice et al., "Turning the Reactivity of Glycosides: Efficient One-pot Oligosaccharide Synthesis," SYNLETT, 781-784, 1995 (Ex. 7);
- 7. A. Kameyama et al., "Total Synthesis of Sialyl Lewis X*," Carbohy-drate Research, 209, c1-c4, 1991 (Ex. 8);
- 8. H. Kondo *et al., "In vitro* action of human and porcine α-amylases. . ," Carbohydrate Research, 204, 207-213, 1990 (Ex. 9);
- 9. H. Kunz et al., "Construction of Disaccharide N-Glycopeptides. . .," Angew. Chem. Int. Ed. Engl., 24, 883-885, 1985 (Ex. 10);
- 10. H. Kunz et al., "Synthesis of O-Glycopeptides of the Tumor-Associated T_N ...," Angew. Chem. Int. Ed. Engl., 25, 360-362, 1986 (Ex. 11);

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- 11. B. Liebe and Horst Kunz, "Solid Phase Synthesis of a Tumor-Associated Sialyl-T_N Antigen Glycopeptide. . . ," Agnew. Chem. Int. Ed. Engl. 33, 618-621, 1997 (Ex. 12);
- 12. H. Lönn, "Synthesis of a Tri- and a Hepta-saccharide. . .," Carbohy-drate Research, 139, 105-113, 1985 (Ex. 13);
- 13. K.C. Nicolaou *et al.*, "Stereocontrolled Synthesis of Sialyl Le^x, . . . ," *J. Chem. Soc., Chem. Commun.*, 870-872, **1991** (Ex. 14);
- 14. P. Schultheiss-Riemann et al., "O-Glycopeptide Synthesis. . .," Angew. Chem. Int. Ed. Engl., 22, 62-63, 1983 (Ex. 15).

Copies of the above-listed documents (Exhibits 2-15) are submitted herewith. In addition, these documents are listed on Form PTO-1449B which is attached hereto (Exhibit 1). To the extent that a document is listed and no copy thereof is attached, then such document is not at present available to the undersigned, or is available in the file of a prior related application relied upon for an earlier filing date under 35 USC §120. 37 CFR §1.98(d).1

Applicants respectfully solicit the Examiner's consideration of the documents and entry into the record of this application. The citation of any document in the

If a listed document is not in the English language and an English translation is readily available, such translation is also attached; if a translation is not attached, it is not readily available to the undersigned. If a foreign language document is cited, and an English language equivalent is known to the undersigned, then such equivalent patent is also cited on the attached form along with the corresponding foreign language patent, and a connecting arrow indicated therebetween; if no such English language equivalent is cited, then none is known to the undersigned.

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present Information Disclosure Statement is not to be construed as an admission that such document is necessarily relevant or is prior art.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

No fee is believed necessary in connection with the filing of this Information Disclosure Statement since it is being filed prior to the issuance of a first Official Action on the merits. 37 CFR §1.97(b)(3). However, if a first Official Action on the merits is mailed on or before the submission date of this Information Disclosure Statement, or any fee is otherwise deemed required, authorization is hereby given to charge the amount of such fee to Deposit Account 50-0540.

Respectfully submitted,

A. David Joran

Registration No./37,858

Attorney for Applicants

KRAMER, LEVIN, NAFTALIS & FRANKEL LLP 919 Third Avenue New York, New York 10022 212-715-9100

| Anne Jan | PTO/SB/08B (10-96) |
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| Patent and Trademark | through 10/31/99. OM8 0651-0031 |

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| INFORMATION DISCLOSURE | | | LOSURE | Application Number | Serial No. 09/042,280 | |
| STATEMENT BY APPLICANT | | Filing Date | January 13, 1997 | | | |
| | | | | First Named Inventor | Samuel J. Danishefsky | |
| | | | | Group Art Unit | 1623 | |
| | luse as many s | heets as nece | essary) | Examiner Name | Lee, H. | |
| eet | 1 | of | 2 | Attorney Docket Number | 1078/1B925US1 | |

| | | OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS | |
|----------------------|--------------|---|----------------|
| Examiner Initials | Cite No.¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Ţ¹ |
| | | V. Bencomo <i>et al.,</i> "Synthesis of glycopeptides having clusters of <i>O</i> -glycosylic disaccharide chains," Carbohydrate Research, 116, c9-c12, 1983 (Ex2) | : |
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| | | M. Elofsson and J. Kihlberg, "Synthesis of Tn and Sialyl Tn building Blocks for Solid Phase Glycopeptide Synthesis," <i>Tetrahedron Letters</i> , 36, 7499-7502, 1995 (Ex. 4) | |
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| | | H. Kondo et al., "In vitro action of human and porcine α-amylases," Carbohydrate Research, 204, | |
| | 1 | H. Kunz et al., "Construction of Disaccharide N-Glycopeptides," Angew.Chem. Int. Ed. Engl., 24, 383-885, 1985 (Ex. 10) | |
| | H | H. Kunz et al., "Synthesis of O-Glycopeptides of the Tumor-Associated T _N ," Angew. Chem. Int. Ed. | |

| Examiner | · · · · · · · · · · · · · · · · · · · | |
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| li - | INFORMATION DISCLOSURE | | | Application Number | Serial No. 09/042,280 | |
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| | | First Named Inventor | Samuel J. Danishefsky | | | |
| | | | | Group Art Unit | 1623 | |
| | luse as many sl | eets as n | ecessary) | Examiner Name | Lee, H. | |
| neet | 2 | of | 2 | Attorney Docket Number | 1078/18925US1 | |

| | | OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS | | |
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| Examiner Initials | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | L2 | |
| | | B. Liebe and Horst Kunz, "Solid Phase Synthesis of a Tumor-Associated Sialyl-T _N Antigen Glycopeptide ," <i>Agnew. Chem. Int.Ed. Engl.</i> 33, 618-621,-1997 (Ex. 12) | <u> </u> | - |
| | | H. Lönn, "Synthesis of a Tri- and a Hepta-saccharide," <i>Carbohydrate Research</i> , <u>139</u> , 105-113, 1985 — | | |
| | | K.C. Nicolaou et al., "Stereocontrolled Synthesis of Sialyl Le*,," J. Chem. Soc., Chem. Commun., 870-872, 1991 (Ex. 14) | | |
| | | P. Schultheiss-Riemann et al., "O-Glycopeptide Synthesis," Angew. Chem. Int. Ed. Engl., 22, 62-63, 1983 (Ex. 15) | | I |
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| STATEMENT BY APPLICANT | | Filing Date Jan | January 13, 1997 | | | |
| | | | | First Named Inventor | Samuel J. Danishefsky | |
| | | | | Group Art Unit | 1623 | |
| ₁ | luse as many s | heets as nec | essary) | Examiner Name | Lee, H. | |
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| Spe | | B. Liebe and Horst Kunz, "Solid Phase Synthesis of a Tumor-Associated Sialyl-T _N Antigen Glycopeptide ," Agnew. Chem. Int.Ed. Engl. 33, 618-621, 1997 (Ex. 12) | |
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